

***In re National Prescription Opiate Litigation: MDL 2804***  
**PLAINTIFFS' MOTION FOR PARTIAL SUMMARY ADJUDICATION OF  
DEFENDANTS' DUTIES UNDER THE CONTROLLED SUBSTANCES ACT**  
**Summary Sheet of Concise Issues Raised**

**Motion Name:** Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act

**Moving Parties:** Plaintiffs Summit County and Cuyahoga County

**Concise Description of Issues:**

*Issue 1:* Do registrants under the Controlled Substances Act have a statutory and/or regulatory duty to halt suspicious orders of opioids until they have investigated and determined that the order is not likely to be diverted?

*Answer:* Yes. The Controlled Substances Act requires registrants to maintain "effective controls against diversion." DEA regulations implementing this duty require registrants to design and operate a system to identify suspicious orders of controlled substances and to report to the DEA suspicious orders so identified. These measures, however, cannot be "effective controls against diversion" if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. For this reason, the DEA has required registrants not merely to identify and report suspicious orders, but also to conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. *See, e.g., Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). The DEA's construction of the CSA to prohibit shipment until suspicious orders have been investigated and cleared is plainly correct, has been recognized by the D.C. Circuit in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017), and has been ratified by Congress, *see* Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"), Public Law 115-271 § 3272.

**Filing Date:** June 25, 2019

**Response Date:** July 29, 2019

**Reply Date:** August 14, 2019